**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NORTH DAKOTA**
**WESTERN DIVISION**

| | |
|---|---|
| PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,<br><br>Plaintiff,<br><br>v.<br><br>MYLYNN TUFTE, in her official capacity as the State Health Officer of North Dakota; MARK J. HARDY, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; FRAN GRONBERG, in her official capacity as the President of the North Dakota Board of Pharmacy; and WAYNE STENEHJEM, in his official capacity as the Attorney General of North Dakota,<br><br>Defendants. | No. ____________________<br><br>**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** |

Plaintiff Pharmaceutical Care Management Association ("PCMA"), on behalf of its members, hereby files this complaint against Mylynn Tufte, in her official capacity as the State Health Officer of North Dakota; Mark J. Hardy, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; Fran Gronberg, in her official capacity as the President of the North Dakota Board of Pharmacy; and Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota, and alleges as follows:

**NATURE OF THE ACTION**

1. PCMA seeks a declaration that two recently passed North Dakota laws, Senate Bill 2258 ("SB2258") and Senate Bill 2301 ("SB2301"),[1] are subject to express preemption under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.*

[1] True and correct copies of SB2258 and SB2301 are attached hereto as **Exhibit A** and **Exhibit B**, respectively.

("ERISA"), and the Medicare Prescription Drug Improvement and Modernization Act of 2003, 42 U.S.C. § 1395w-101 *et seq.* ("Medicare Part D"). SB2258 and SB2301 amend the North Dakota Food, Drug, and Cosmetic Act, N.D. Cent. Code § 19-02.1-01 *et seq.*, to impose onerous new restrictions on pharmacy benefit managers ("PBMs") operating on behalf of, *inter alia*, ERISA-covered benefit plans and Medicare Part D prescription drug plans in North Dakota. SB2258 and SB2301 will go into effect on August 1, 2017.

**JURISDICTION AND VENUE**

2. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this case raises questions arising under federal law.

3. This Court has personal jurisdiction over Defendants because Defendants reside within the District of North Dakota.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events giving rise to these claims occurred in this district and Defendants reside in North Dakota.

**PARTIES**

5. PCMA is the national trade association representing PBMs. PCMA's PBM member companies administer prescription drug benefits for more than 230 million Americans covered by ERISA and non-ERISA benefit plans. The ERISA benefit plans with which PCMA's members contract include both insured and self-funded benefit plans sponsored by employers and labor unions. The non-ERISA benefit plans with which PCMA's members contract include Medicare Part D prescription drug plans and health plans sponsored by state and local governments that contract directly for PBM services. PCMA's principal place of business is in Washington, D.C.

6. Defendant Mylynn Tufte is the State Health Officer of North Dakota. The State Health Officer serves as the head of the North Dakota Department of Health. Under chapter

19-02.1 of the North Dakota Century Code, the North Dakota Department of Health is responsible for referring violations of SB2258 and SB2301 for prosecution. N.D. Cent. Code. § 19-02.1-06; *see also* N.D. Cent. Code § 19-01-06 (providing that the Department of Health "shall enforce" the provisions in title 19 of the Century Code).[2] The State Health Officer is a resident of North Dakota and is being sued solely in her official capacity.

7. Defendant Mark J. Hardy is the Executive Director of the North Dakota Board of Pharmacy. Under North Dakota law, the Executive Director of the Board of Pharmacy performs the administrative functions of the board, including in litigation. *See* N.D. Cent. Code § 43-15-06(2)–(3). Under chapter 19-02.1 of the North Dakota Century Code, the Board of Pharmacy is responsible for referring violations of SB2258 and SB2301 for prosecution. N.D. Cent. Code. § 19-02.1-06. The Executive Director of the Board of Pharmacy is a resident of North Dakota and is being sued solely in his official capacity.

8. Defendant Fran Gronberg is the President of the North Dakota Board of Pharmacy. Under chapter 19-02.1 of the North Dakota Century Code, the Board of Pharmacy is responsible for referring violations of SB2258 and SB2301 for prosecution. N.D. Cent. Code. § 19-02.1-06. The President of the Board of Pharmacy is a resident of North Dakota and is being sued solely in her official capacity.

9. Defendant Wayne Stenehjem is the Attorney General of North Dakota. Under North Dakota law, the Attorney General shall "[c]onsult with and advise the several state's attorneys in matters relating to the duties of their office." N.D. Cent. Code § 54-12-01(4). Under chapter 19-02.1 of the North Dakota Century Code, the state's attorneys are responsible for prosecuting violations of SB2258 and SB2301 upon referral from the State Health Officer or the

[2] Both SB2258 and SB2301 are to be codified in chapter 19-02.1 of the North Dakota Century Code. SB2258 § 1; SB2301 § 1.

Board of Pharmacy. N.D. Cent. Code. § 19-02.1-06. The Attorney General is a resident of North Dakota and is being sued solely in his official capacity.

10. Defendants, and those subject to Defendants' supervision, direction, and/or control, are responsible for the enforcement of SB2258 and SB2301.

## BACKGROUND

### A. The Nature of the PBM Business

11. Many North Dakota residents receive their prescription drug benefits through health plans, including self-funded and insured health benefit plans sponsored by employers and employee organizations; health plans offered by nonprofit hospital or medical services corporations, health insurers, and health maintenance organizations; health plans sponsored, supported, or approved by federal, state, and local governments; and other benefit plans (collectively, "health plans").

12. Health plans typically provide prescription drug benefits to their members through contracts with PBMs ("PBMs"). Health plans utilize PBMs to perform essential functions related to managing prescription drug benefits, including negotiating drug prices with pharmaceutical manufacturers and retail pharmacies, establishing a network of pharmacies to fill prescriptions, and processing and paying claims for prescriptions. PBMs are able to leverage economies of scale that benefit health plans and their members, and their services allow health plans to avoid the massive effort needed to reliably and effectively manage prescription drug benefits.

13. PBMs offer health plans a variety of services and programs in addition to handling claims processing for prescription drug benefits to contain and lower costs, including:

a. *Negotiating Discounted Reimbursements with Pharmacies*. PBMs typically design retail pharmacy networks and negotiate with pharmacies to set a competitive rate at which the PBM will reimburse for each prescription that a pharmacy fills.

b. *Encouraging Generics and Less Expensive Brands*. PBMs use several tools to encourage dispensing of generics and less expensive brands, including formularies, which are lists of prescription drugs that are clinically reviewed and approved by a pharmacy and therapeutic committee and are covered by a health plan. PBMs also use a variety of other tools to encourage cost-effective use of prescription drugs, including tiered cost sharing, prior authorization and step therapy protocols, generic incentive programs, consumer education, and physician outreach.

c. *Using Cutting-Edge Tools to Improve Adherence*. PBMs conduct drug utilization reviews to reduce waste. PBMs also implement patient adherence programs to help patients stick to their prescription regimens. Both programs improve clinical outcomes while simultaneously managing prescription volume and expenditures.

d. *Improving Quality and Safety*. PBMs promote the use of technology to improve quality and safety by preventing drug duplication and dangerous drug-to-drug interactions.

14. PBMs create pharmacy networks by entering into contracts with pharmacies. These networks are essential to PBMs' contracts with health plans because they allow PBMs to guarantee that a health plan's members—individual consumers and their families—will receive adequate service, including accessibility at the level required by the Centers for Medicare and Medicaid Services ("CMS") for Medicare Part D plan members.

15. The pharmacies in a PBM's network fill prescriptions for health plan members using prescription drugs pharmacies have purchased on their own directly from wholesalers or manufacturers. When a health plan member goes to a pharmacy to fill a prescription, the pharmacy checks with the PBM to confirm the applicable plan design for the plan member to

determine coverage and copayment information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually agreed rate minus the copay collected by the pharmacy from the plan member. The PBM then separately bills the health plan at the rate negotiated between the PBM and the health plan.

16. Because PBMs provide some of the best tools in the marketplace to administer prescription drug benefits, control prescription drug costs, and maximize patient outcomes, nearly all plans providing prescription drug coverage utilize PBM services.

**B. SB2258's and SB2301's Requirements**

17. The Governor of North Dakota recently signed into law two pieces of legislation that regulate the operations of PBMs in North Dakota: SB2258 and SB2301. Both laws will become effective on August 1, 2017. These laws impose several new, significant, and interrelated regulations on PBMs and third-party payers, including health plans, operating in North Dakota.

18. SB2258 changes the prior law in several respects, including the following:

a. It prohibits PBMs and third-party payers from charging pharmacies certain fees, including fees that are imposed after the point of sale, not reported on the remittance advice for a claim, or not apparent at the time of claim processing. SB2258 § 1(2).

b. It limits the performance standards that PBMs and third-party payers may use to evaluate pharmacy performance and the fees PBMs and third-party payers may impose based on those standards. SB2258 § 1(3).

c. If a patient pays a copayment, it requires pharmacies and providers to "retain the adjudicated cost" and bars PBMs and third-party payers from "redact[ing] the adjudicated cost." SB2258 § 1(4). PCMA understands "adjudicated cost" to refer to the amount the PBM or third-party payer reimburses the pharmacy for the prescription.

d. It provides that a pharmacy may disclose to a "plan sponsor" (as defined in SB2258) or to a plan member the amount of the adjudicated reimbursement paid to the pharmacy for a prescription. SB2258 § 1(5).

e. It provides that a pharmacy may disclose "relevant" information to a patient, which may include reimbursement information, and prohibits PBM–pharmacy contracts that prevent such disclosure. SB2258 § 1(7).

f. It authorizes pharmacies to "mail or deliver drugs to a patient as an ancillary service of a pharmacy," and thereby appears to prohibit PBM–pharmacy contracts barring or limiting mail or other forms of delivery of prescription drugs. SB2258 § 1(8).

g. It prohibits contracts that provide that a pharmacy may not charge a shipping and handling fee to a patient. SB2258 § 1(9).

h. It requires a PBM or third-party payer to disclose to a pharmacy "the processor control number, bank identification number, and group number" for each pharmacy network it administers on demand by a pharmacy. SB2258 § 1(10).

i. It prohibits a PBM or third-party payer from imposing accreditation and recertification standards beyond preexisting federal and state licensing requirements. SB2258 § 1(11).

19. SB2301 also changes the prior law in several respects, including the following:

a. It obligates a PBM or third-party payer that has an ownership interest in a pharmacy to disclose the difference between the amount paid to the pharmacy and the amount charged to the plan sponsor on request of the plan sponsor. SB2301 § 1(2).

b. It prohibits a PBM from having an ownership interest in a patient assistance program or mail-order specialty pharmacy unless the PBM agrees "not to participate

in a transaction that benefits [the PBM] instead of another person owed a fiduciary duty." SB2301 § 1(3).

c. It prohibits a PBM or third-party payer from imposing accreditation standards beyond preexisting federal and state licensing requirements. SB2301 § 1(4). This provision mirrors the provision in SB2258 § 1(11).

d. It authorizes a pharmacy to dispense "any and all drugs allowed" under its license. SB2301 § 1(5).

20. Violations of SB2258 and SB2301 are punishable criminally as class B misdemeanors.

**C. SB2258 and SB2301 Harm PBMs and the Plans They Serve**

21. SB2258 and SB2301 harm PBMs and, by extension, the health and prescription drug benefit plans they serve by restricting their choices relating to plan structure and administration. These restrictions also threaten the safety of North Dakota plan members served by PBMs.

22. First, SB2258 and SB2301 force health plans and the PBMs that provide services to them to modify their interstate contracts to ensure that North Dakota-based plan members, as well as plan members that visit North Dakota, receive benefits that comply with SB2258 and SB2301.

23. Second, SB2258's limitations on fees, including performance-based fees, and the performance standards that PBMs employ to measure pharmacy performance threaten the integrity and quality of PBMs' pharmacy networks.

24. PBM–pharmacy contracts may provide that a pharmacy will pay certain fees that, among other things, support access to a PBM's IT systems that allow pharmacies to fill

prescriptions and also maintain pharmacy help lines, benefit manuals, and other PBM services. Although SB2258's requirements are unclear, SB2258 may preclude these fees.

25. In addition, PBM–pharmacy contracts also often provide for the payment of fees related to pharmacy performance metrics. Those performance standards may mirror those of a third-party quality management platform, but, in many cases, they do not. PBMs impose different or enhanced performance standards to ensure a high performing pharmacy network or to measure performance metrics other than those measured by third-party platforms; at times, health plans themselves require such performance standards. Using proprietary performance standards also avoids the substantial cost to health plans, PBMs, and pharmacies of implementing a third-party quality management platform.

26. These performance standards and related fees hold pharmacies accountable for a variety of important activities, such as generic and cost-effective dispensing, improving adherence (i.e., ensuring that patients actually take the drugs they are prescribed), reducing inappropriate drug use, accurately dispensing drugs, and promptly answering calls from plan members.

27. These performance standards correlate to the health outcomes of a health plan's members and health plan finances. For instance, adherence directly impacts plan members' health outcomes because one must take a prescription drug in the prescribed manner and for the prescribed time for it to have its intended effect. Likewise, a pharmacy's rate of prescribing generic drugs, which are cheaper than their branded equivalents, directly impacts a health plan's expenses.

28. By their nature, these performance-based fees are unknowable at the time a prescription is filled or a claim is initially processed. In many cases, they exceed the amount of

the dispensing fee provided in the PBM–pharmacy contract, which also serves to encourage the dispensing of lower-priced prescription drugs. SB2258 precludes these fees.

29. SB2258 also limits what is often referred to as "direct and indirect remuneration" ("DIR"), which is a term under Medicare Part D for post-point-of-sale changes to, among other things, the amount a health plan pays a pharmacy for a drug insofar as those changes cannot reasonably be ascertained at the point of sale. DIR encompasses performance-based fees, among other things, that meet that criterion (as they often do). SB2258 precludes these fees as well.

30. Third, SB2258's requirements regarding shipping and handling fees limit health plans' and PBMs' choices in designing benefits for their members. PBM–pharmacy contracts generally contain limits on fees that pharmacies may charge to plan members, including shipping and handling fees, in order to ensure that plan members receive a consistent level of benefits across pharmacies in a PBM's network and to ensure that they have cost-effective access to prescription drugs.

31. Fourth, SB2258's and SB2301's disclosure requirements impinge upon PBMs' ability to manage the reporting and disclosure of their proprietary information. PBMs rely on their proprietary pricing methodologies to contain prescription drug costs and conduct their businesses. PBMs' pricing methodologies are unique to each PBM and are not generally known or readily ascertainable in the PBM industry. The PBM industry is fiercely competitive. As one of their most valuable tools in providing cost-effective solutions to their customers, PBMs consider their pricing methodologies (and related reimbursement amounts) to be proprietary trade secrets and protect them as such.

32. Similarly, PBM–pharmacy contracts typically preclude a pharmacy from disclosing to the patient the amount of a reimbursement. Among other reasons, PBMs do this to

prevent pharmacies from putting plan members (patients) in the middle of a dispute between the PBM and the pharmacy over the amount of the negotiated reimbursement the pharmacy receives and to ensure that plan members have a positive, consistent experience across pharmacies in a PBM's network. PBM–pharmacy contracts contain alternative mechanisms to resolve pharmacy grievances about the amount of a reimbursement, such as an appeal to the PBM, rather than complaints to plan members who have no control over the amount of reimbursements.

33. The requirement that PBMs and health plans disclose to pharmacies the processor control number, bank identification number, and group number for each network administered by the PBM or health plan upon request from a pharmacy imposes substantial administrative burdens and mandates the disclosure of proprietary information. This provision requires each PBM to prepare a single document containing the routing information for claims to all of the health plans served by that PBM nationwide, which typically number in the thousands. PBMs do not maintain this information in aggregate form, and it may change daily. In addition, this requirement effectively requires PBMs to identify all of their customers—health plans—nationwide in a single list. SB2258 requires PBMs to disclose this proprietary information to any pharmacy, even pharmacies with whom PBMs have not contracted.

34. Fifth, SB2258's and SB2301's prohibition of pharmacy accreditation and recertification standards that exceed preexisting federal and state licensing requirements and authorization for pharmacies to dispense all drugs under their licenses substantially limits health plan and PBM choices in designing pharmacy networks and threatens plan member safety.

35. These requirements bar PBMs and health plans from employing enhanced accreditation standards—such as the widely used URAC[3] Specialty Pharmacy Accreditation—to designate a pharmacy's ability to provide specialty services and to limit the dispensing of high-value specialty drugs to those pharmacies. Specialty pharmacies manage drug regimens for patients with complex, chronic, or rare medical conditions such as multiple sclerosis, hepatitis C, cystic fibrosis, and hemophilia. These pharmacies specialize in the unique storage and shipping requirements that oral, injectable, inhalable, and infusible products require, as well as the unique drug-usage counseling and follow-up procedures applicable to specialty pharmacy patients. Because of such unique handling requirements and the complexities of caring for patients with complex, chronic, or rare conditions, the average pharmacy is often ill equipped to dispense specialty pharmaceuticals and provide an appropriate level of patient care. Indeed, drug manufacturers themselves often impose restrictions on the specialty pharmacies that may dispense their drugs.

36. A pharmacy's willingness to follow enhanced accreditation standards demonstrates the pharmacy's commitment to safety and establishes the pharmacy as capable of providing the full suite of services needed to serve patients taking specialty drugs, such as 24-hour access to health professionals specially trained in specific complex diseases and tracking outcomes for specific patients. By barring enhanced accreditation standards and authorizing pharmacies to dispense all drugs under their license, SB2258 and SB2301 impose immediate, serious risks to patient safety in North Dakota.

---

[3] URAC is an independent, nonprofit organization that "develop[s] evidence-based measures and standards through inclusive engagement from a range of stakeholders." *About URAC*, URAC, https://www.urac.org/about-urac/about-urac/ (last visited July 10, 2017).

37. Similarly, PBMs often require pharmacies to satisfy more mundane—but no less important—criteria to participate in their networks. For instance, PBM–pharmacy contracts typically require pharmacies to carry insurance. North Dakota, like many other states, does not require insurance to be licensed as a pharmacist or to receive a permit to operate a pharmacy. N.D. Cent. Code §§ 43-15-15, 43-15-35. Likewise, a PBM typically will not admit a pharmacy that has lost its license in one state into its network in another state, even though that pharmacy may satisfy the criteria for licensure in the latter state. Furthermore, even basic patient safety issues may not preclude a pharmacy from obtaining a license from the state but can and should prevent the pharmacy from gaining admission to a PBM's network.

38. PBM–pharmacy contracts also require pharmacies to abide by the formulary rules applicable to a plan member. Formularies help minimize prescription drug costs, improve patient access to affordable care, and ensure access to clinically appropriate medication. Health plans select the formularies applicable to their plan members. Although the statute is unclear, the authorization for pharmacies to dispense all drugs allowed under their licenses, insofar as it requires PBMs to reimburse for any drug dispensed by a pharmacy, appears to bar the use of formularies, substantially increasing costs to health plans and their members.

39. Sixth, SB2258's blanket authorization for all pharmacies, regardless of their experience or qualifications, to deliver or mail prescriptions to patients impinges on network design and risks patient safety. It is of critical importance that pharmacies delivering medications through either home delivery or the mail have the relevant licensure (such as being licensed in *both* the state in which they are located *and* the state into which they are shipping medications) and the experience and expertise to ensure patient safety. For that reason, some health plans do not provide any access to prescription drugs by mail or home delivery. If a health plan provides

access to prescription drugs by mail or home delivery, it typically limits the pharmacies authorized to dispense drugs through such mechanisms to ensure that only drugs that are capable of delivery are dispensed in that manner; that they are packaged and transported so as to maintain their quality and potency; that pharmacies use appropriate controls to ensure that drugs—which may be controlled substances—are delivered to the correct person; and that those pharmacies comply with all applicable regulatory requirements.

40. Further, given the different reimbursement structures for retail pharmacies and mail-order pharmacies, PBMs that permit retail pharmacies to dispense drugs via mail or home delivery typically limit the amount of prescriptions that a pharmacy may dispense on a mail-order or home delivery basis.

41. Seventh, SB2301's limitations on the transactions in which PBMs and health plans may participate if they have an ownership interest in a patient assistance program or mail-order specialty pharmacy impacts plan structure and patient safety. Although this requirement is less than completely clear, its apparent purpose is to prevent PBMs from providing prescription drug benefits through mail-order pharmacies in which they own an interest. This provision directly impacts patient care in North Dakota because certain specialty drugs are available only from mail-order pharmacies in which PBMs have an interest. The end result is that certain lifesaving drugs are no longer available to health plan members that reside in North Dakota or happen to travel to North Dakota and require treatment.

42. SB2258 and SB2301 present an interrelated attack on PBMs, and their provisions are nonseverable.

**D. A Justiciable Controversy Now Exists Between PCMA and Defendants**

43. As SB2258 and SB2301 will become effective in just a few weeks—on August 1, 2017—the claims raised by PCMA in this complaint are fit for judicial decision today, and are

not speculative or contingent. Indeed, although SB2258 and SB2301 have not yet become effective, the passage of the laws has forced PCMA's members already to begin the process of revising their business practices—at substantial expense—so they are in compliance with SB2258's and SB2301's requirements as of their effective date.

44. PCMA has standing to sue on behalf of its members, which comprise America's leading PBMs. PCMA's purposes include advancing the common interests of PBMs. PCMA fulfills that purpose in part by bringing suit against governmental authorities to defend the PBM industry from damaging laws and regulations. SB2258 and SB2301 impose damaging new requirements on PBMs operating in North Dakota.

45. PCMA's claims—which attack SB2258 and SB2301 on legal, not factual grounds—and relief requested herein do not require the participation of PCMA's members.

## CLAIMS FOR RELIEF

### Count One—ERISA "Reference To" Express Preemption (29 U.S.C. § 1144(a))

46. PCMA repeats and realleges each and every allegation contained in paragraphs 1 through 45 as if fully set forth herein.

47. ERISA is a comprehensive federal statute that regulates employee benefit plans and is designed to ensure uniform national treatment of such plans.

48. To serve the federal interest in the uniform national treatment of employee benefit plans, Congress included a broad express preemption provision in ERISA. That provision states that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a).

49. A state law "relates to" ERISA if, *inter alia*, that law has a "reference to" ERISA plans.

50. SB2258 and SB2301 both refer implicitly to ERISA plans and therefore contain a prohibited "reference to" ERISA plans.

51. Specifically, SB2258 and SB2301 both regulate "third-party payer[s]" and "pharmacy benefits manager[s]." SB2258 § 1, SB2301 § 1. North Dakota law defines "third-party payer" as including "an organization other than the patient or health care provider involved in the financing of personal health services." N.D. Cent. Code § 19-03.6-01(6). A "pharmacy benefits manager," in turn, includes

> [a] person that performs pharmacy benefits management and includes any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, *third-party payer*, or health program administered by a state agency.

*Id.* § 19-03.6-01(4) (emphasis added). These definitions facially encompass ERISA-covered health plans and PBMs administering prescription drug benefits on behalf of such plans.

52. SB2258 and SB2301 also refer to ERISA-covered entities through their references to a "plan sponsor." *See* SB2258 § 1(1)(b), (5); SB2301 § 1(1)(b), (2). The definition of "plan sponsor" encompasses sponsors of ERISA-covered plans. N.D. Cent. Code § 19-03.6-01 (defining "plan sponsor" to mean, *inter alia*, "the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization"); *see also* 29 U.S.C. § 1002(16)(B) (for purposes of ERISA, defining "plan sponsor" to mean, *inter alia*, "(i) the employer in the case of an employee benefit plan established or maintained by a single employer, [or] (ii) the employee organization in the case of a plan established or maintained by an employee organization").

53. SB2258 and SB2301 are expressly preempted by ERISA.

54. PCMA has no adequate remedy at law available against Defendants for the infringement of the statutorily protected preemption rights its members will imminently suffer when SB2258 and SB2301 take effect on August 1, 2017.

**Counts Two through Thirteen—ERISA "Connection With" Express Preemption (29 U.S.C. § 1144(a))**

55. PCMA repeats and realleges each and every allegation contained in paragraphs 1 through 54 as if fully set forth herein.

56. For purposes of ERISA's express preemption provision, a state law also "relates to" ERISA if, *inter alia*, that law has a "connection with" ERISA plans.

57. SB2258 and SB2301 regulate, *inter alia*, PBMs administering pharmacy benefits on behalf of health plans covered by ERISA and therefore function as a regulation of such ERISA-covered health plans. SB2258 and SB2301 also directly regulate ERISA-covered health plans that self-administer their pharmacy benefits.

58. The following provisions of SB2258 and SB2301 have a connection with ERISA plans because they govern central matters of plan administration and structure:

| Count | Bill Section | Summary of Regulation | Example of Connection with ERISA Plans |
|---|---|---|---|
| 2 | SB2258 § 1(2) | Limitations on fees charged by PBMs. | Regulates plan structure, including the calculation of benefit levels and making disbursements for such benefits. |
| 3 | SB2258 § 1(3) | Limitations on the performance standards PBMs may use to evaluate pharmacies and the fees that PBMs may impose related to those standards. | Regulates plan structure, including pharmacy network composition, calculation of benefit levels, and making disbursements for such benefits. |

| Count | Bill Section | Summary of Regulation | Example of Connection with ERISA Plans |
|---|---|---|---|
| 4 | SB2258 § 1(4) | The requirements that pharmacies and providers "retain the adjudicated cost" and that PBMs not "redact" the "adjudicated cost" of the prescription from a patient that pays a copayment.<br><br>PCMA challenges § 1(4) insofar as it (a) bars PBMs from recouping any amount of a reimbursement or a copayment from a pharmacy or provider or (b) requires PBMs to disclose or bars PBMs from not disclosing the amount of the adjudicated cost to anyone other than the pharmacy.[4] | Regulates reporting, disclosure, and plan structure. |
| 5 | SB2258 § 1(5) | The authorization for pharmacies to disclose to plan sponsors and plan members the reimbursement amounts paid to them for a prescription. | Regulates reporting, disclosure, and plan structure. |
| 6 | SB2258 § 1(7) | The authorization for pharmacies to disclose "relevant" information to a patient, and the related bar on contracts that prohibit pharmacies from doing so.<br><br>PCMA challenges SB2258 § 1(7) insofar as it authorizes pharmacies to disclose reimbursement information to plan members. | Regulates reporting, disclosure, and plan structure. |

[4] PCMA does not challenge section 1(4)'s prohibition on charging copayments that exceed the cost of a medication.

| Count | Bill Section | Summary of Regulation | Example of Connection with ERISA Plans |
|---|---|---|---|
| 7 | SB2258 § 1(8) | The authorization for pharmacies to mail or deliver drugs to a patient as an ancillary service.<br><br>PCMA challenges SB2258 § 1(8) insofar as it authorizes pharmacies to mail or deliver drugs regardless of their agreements with PBMs. | Regulates plan structure and provider network and benefit design. |
| 8 | SB2258 § 1(9) | The prohibition on contracts that provide that a pharmacy may not charge a shipping and handling fee to a patient. | Regulates plan structure, including the calculation of benefit levels and making disbursements for such benefits. |
| 9 | SB2258 § 1(10) | The requirement that PBMs and third-party payers provide to pharmacies "the processor control number, bank identification number, and group number" for each pharmacy network they administer. | Regulates reporting and disclosure. |
| 10 | SB2258 § 1(11);<br>SB2301 § 1(4) | The bar on imposing pharmacy accreditation standards other than preexisting federal and state requirements. | Regulates plan structure and provider network design. |
| 11 | SB2301 § 1(2) | The requirement that, upon request, PBMs and third-party payers that have an ownership in a pharmacy disclose to plan sponsors the "difference between the amount paid to a pharmacy and the amount charged" to a plan sponsor. | Regulates reporting and disclosure. |

| Count | Bill Section | Summary of Regulation | Example of Connection with ERISA Plans |
|---|---|---|---|
| 12 | SB2301 § 1(3) | The bar on a PBM having an ownership interest in a patient assistance program or mail-order specialty pharmacy unless the PBM agrees "not to participate in a transaction that benefits [the PBM] instead of another person owed a fiduciary duty." | Regulates plan structure. |
| 13 | SB2301 § 1(5) | The authorization for pharmacies to dispense any and all drugs allowed under their license.<br><br>PCMA challenges SB2258 § 1(8) insofar as it authorizes pharmacies to dispense drugs regardless of their agreements with PBMs. | Regulates plan structure and provider network and benefit design. |

59. In addition, each of the foregoing interferes with nationally uniform plan administration by requiring ERISA-covered health plans and PBMs to establish unique contractual arrangements for such plans that are tailored to the requirements of SB2258 and SB2301.

60. The foregoing provisions of SB2258 and SB2301 are therefore expressly preempted by ERISA.

61. PCMA has no adequate remedy at law available against Defendants for the infringement of the statutorily protected preemption rights its members will imminently suffer when SB2258 and SB2301 take effect on August 1, 2017.

**Count Fourteen—Medicare Part D Express Preemption**
**(42 U.S.C. § 1395w-112(g))**

62. PCMA repeats and realleges each and every allegation contained in paragraphs 1 through 61 as if fully set forth herein.

63. Like ERISA, Medicare Part D contains an express preemption provision. The express preemption provision applicable to Medicare Part D provides that "[t]he standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to . . . plans which are offered by . . . organizations under this part." 42 U.S.C. § 1395w-26(b)(3); *id.* § 1395w-112(g) (extending § 1395w-26(b)(3) to Medicare Part D plans).

64. The Social Security Act provisions relating to Medicare Part D and related CMS regulations comprehensively regulate the operations of Medicare Part D plans and, by extension, PBMs serving those plans. *See* 42 C.F.R. § 423.505(i) (requirements for contracts between Medicare Part D plan sponsors and, among other parties, first-tier entities like PBMs). Among other things:

a. The Social Security Act bars the government from interfering in negotiations among pharmacies and Medicare Part D plans and from instituting a price structure for the reimbursement of Medicare Part D drugs. 42 U.S.C. § 1395w-111(i)(1)–(2).

b. The Social Security Act regulates disclosures to Medicare Part D beneficiaries. *See* 42 U.S.C. § 1395w-104(a); *see also* 42 U.S.C. § 1395w-104(k); 42 C.F.R. §§ 423.128, 423.132.

c. The Social Security Act and CMS regulations regulate access to Medicare Part D drugs, including pharmacy network access and formulary development. *See, e.g.*, 42 U.S.C. § 1395w-104(b); 42 C.F.R. § 423.120.

d. CMS regulations establish a quality evaluation system and performance standards for Medicare Part D. *See, e.g.*, 42 C.F.R. § 423.153.

e. CMS regulations explicitly contemplate the payment of direct and indirect remuneration. *See* 42 C.F.R. § 423.308 (including "direct and indirect remuneration" in the definition of "actually paid").

f. CMS regulations govern the inclusion of mail-order pharmacies in Medicare Part D networks and the manner in which Medicare Part D beneficiaries may access prescription drugs. *See* 42 C.F.R. § 423.120(a)(3).

65. SB2258 and SB2301 do not relate to licensing or plan solvency.

66. SB2258 and SB2301 are laws with respect to Medicare Part D plans because they specifically regulate health plans, including Medicare Part D plans, either directly or through PBMs.

67. Accordingly, SB2258 and SB2301 are expressly preempted by Medicare Part D.

68. PCMA has no adequate remedy at law available against Defendants for the infringement of the statutorily protected preemption rights its members will imminently suffer when SB2258 and SB2301 take effect on August 1, 2017.

**REQUEST FOR RELIEF**

WHEREFORE, PCMA respectfully prays that this Court:

(1) declare that SB2258 is expressly preempted by ERISA,

(2) declare that SB2301 is expressly preempted by ERISA,

(3) declare that SB2258 is expressly preempted by Medicare Part D,

(4) declare that SB2301 is expressly preempted by Medicare Part D,

(5) permanently enjoin Defendants and their agents, servants, employees, and all persons in active concert or participation with them from taking any action under or to enforce SB2258 and SB2301, and

(6) grant PCMA such additional or different relief as it deems just and proper.

Dated: July 11, 2017

Respectfully submitted,

By: */s/ Robert B. Stock*
Robert B. Stock

M. Daniel Vogel (N.D. Bar #03198)
Robert B. Stock (N.D. Bar #05919)
Neil J. Roesler (N.D. Bar #06783)
VOGEL LAW FIRM
218 Northern Pacific Avenue
Fargo, ND 58107
(701) 237-6983
dvogel@vogellaw.com
rstock@vogellaw.com
nroesler@vogellaw.com

M. Miller Baker (*pro hac vice forthcoming*)
Charles R. Quigg (*pro hac vice forthcoming*)
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
mbaker@mwe.com
cquigg@mwe.com

*Counsel for Pharmaceutical Care Management Association*